5

20

## **CLAIMS**

- 1. Biologically inactive cushioning beads for making solid shaped articles containing biologically active ingredients by compression, comprising at least one compressible cushioning component consisting essentially of a microcrystalline hydrocarbon wax or a natural wax, the said wax being at least 30% by weight of the biologically inactive cushioning beads.
- Cushioning beads for making solid shaped articles containing biologically active
  ingredients by compression, comprising at least one compressible cushioning component comprising a hydrocarbon wax or a natural wax, the cushioning beads including at least 5% by weight of an excipient dispersed throughout the hydrocarbon or natural wax.
- 15 3. Cushioning beads according to claim 2, wherein the hydrocarbon wax is a microcrystalline wax.
  - 4. Cushioning beads according to claim 1 or 3, wherein the microcrystalline hydrocarbon wax or natural wax has a dynamic viscosity at 98.9°C (DIN 52007) greater than or equal to 2 mPa.s.
    - 5. Cushioning beads according to claim 1, 3 or 4, wherein the microcrystalline hydrocarbon wax or natural wax has a congealing point between 50°C and 90°C.
- 6. Cushioning beads according to any of claims 1, 3, 4 or 5, wherein the microcrystalline hydrocarbon wax or natural wax comprises a mixture of 30 to 90% by weight of linear hydrocarbons and 10 to 70% by weight of branched hydrocarbons.
- 7. Custioning beads according to any of claims 1 or 3 to 6, wherein over 98% of the molecules of the microcrystalline hydrocarbon wax or natural wax have a molecular chain length, as determined by high temperature capillary gas chromatography, ranging from 20 to 75 carbon atoms.

5

10

15

20

- 8. Cushioning beads according to any of claims 1 or 3 to 7, wherein the distribution of molecular chain lengths within the microcrystalline hydrocarbon wax or natural wax is such that less than 6% of the molecules have less than 25 carbon atoms, 6 to 50% of the molecules have 25 to 29 carbon atoms, 20 to 45% of the molecules have 30 to 34 carbon atoms and 7 to 70% of the molecules have at least 35 carbon atoms.
- 9. Cushioning beads according to any of claims 1 or 3 to 5, wherein the microcrystalline hydrocarbon wax is the product of catalytic polymerization of ethylene or copolymerization of ethylene with minor amounts of linear alpha-olefins having from 3 to 12 carbon atoms (e.g. propylene, 1-butene, 1-bexene, 1-octene) or maleic anhydride.
- 10. Cushioning beads according to claim 9, wherein the microcrystalline hydrocarbon wax has a number average molecular weight from about 500 to about 1,200.
  - 11. Cushioning beads according to any of claims 1 or 3 to 5, wherein the wax is a natural wax selected from carnauba wax, candelilla wax, palm wax, lignite wax, ozokerite, lardaceine, ceresine wax and China wax.
  - 12. Cushioning beads according to any of claims 1, or 3 to 5, comprising compounds selected from saturated hydrocarbons having from 25 to 31 carbon atoms, saturated alcohols having from 25 to 31 carbon atoms, saturated monocarboxylic acids having from 25 to 31 carbon atoms, esters obtained from the said alcohols and monocarboxylic acids and having from 50 to 62 carbon atoms, and their mixtures.
  - 13. Cushioning beads according to claim 12, comprising compounds selected from neocetylic alcohol,neocerotic acid, ceryl cerotate, montanic acid, myricic alcohol, cerylic alcohol, cerylic acid and myricyl cerotate and their mixtures.
  - 4/Cushioning beads according to any of claims 1 to 13, further including up to 70% by weight of another biologically inactive cushioning component or a pharmaceutically acceptable additive selected from colorants, sweeteners,

30

25

5

15

20

flavoring agents, buffering agents, fillers, disintegrating agents and swellable materials.

- 15. Cushioning beads according to any of claims 1 to 14, further including at least 5% by weight of a disintegrating agent.
  - 16. Cushioning beads according to any of claims 1 to 15, wherein the hydrocarbon wax or natural wax is a water-insoluble wax.
- 17. Cushioning beads according to any of claims 1 to 16, having an average particle size of 0.5 to 2.0 mm.
  - 18. A solid shaped article containing biologically active ingredient-loaded beads and further comprising cushioning beads according to any of claims 1 to 17.
  - 19. A solid shaped article according to claim 18, wherein a coating material is applied to the biologically active ingredient-loaded beads for controlling or sustaining the release properties of the biologically active ingredient or for taste masking or for imparting resistance to gastric fluid.
  - 20. A solid shaped article according to claim 19, wherein the coating is brittle.
  - 21. A solid shaped article according to claim 18, 19 or 20 wherein the weight ratio of cushioning beads to biologically active ingredient-loaded beads is between 30:70 and 70:30.
  - 22. Use of a microcrystalline hydrocarbon wax or a natural wax as a cushioning component for making solid shaped articles containing therapeutically active ingredients.
  - 23. A method for treating a plant in need of a biological treatment by bringing the said plant into contact with an efficient amount of a biologically active ingredient in the form of a solid shaped article containing biologically active ingredient-loaded beads

30

25

and further comprising biologically inactive cushioning beads comprising at least one compressible cushioning component consisting essentially of a microcrystalline hydrocarbon wax or a natural wax, the said wax being at least about 30% by weight of the biologically inactive cushioning beads.

5

10

25

- 24. A method for treating a mammal in need of a medication by administering to said mammal an efficient amount of said medication containing a biologically active ingredient in the form of a solid shaped article containing biologically active ingredient-loaded beads and further comprising biologically mactive cushioning beads comprising at least one compressible cushioning component consisting essentially of a microcrystalline hydrocarbon wax or a natural wax, the said wax being at least about 30% by weight of the biologically inactive cushioning beads.
- 25. A method for treating a plant in need of a biological treatment by bringing the said plant into contact with an efficient amount of a biologically active ingredient in the form of a solid shaped article containing biologically active ingredient-loaded beads and further comprising biologically inactive cushioning beads comprising at least one compressible cushioning component comprising a hydrocarbon wax or a natural wax, the cushioning beads also including at least 5% excipient dispersed throughout the wax.
  - 26. A method for treating a mammal in need of a medication by administering to said mammal an efficient amount of said medication containing a biologically active ingredient in the form of a solid shaped article containing biologically active ingredient loaded beads and further comprising biologically inactive cushioning beads comprising at least one compressible cushioning component comprising a hydrocarbon wax or a natural wax, the cushioning beads including at least 5% excipient dispersed throughout the wax.

odi albs